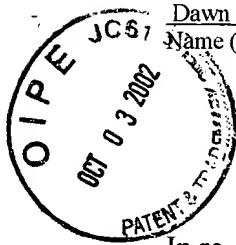


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Dawn M. Berry
Name (Print)

Dawn M. Berry
Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

DAMARLA, et al.

Application Number: 09/536,351

Filed: March 27, 2000

) Art Unit: 1616

) Examiner: Levy, N.

For: STORAGE STABLE PESTICIDE FORMULATIONS CONTAINING AZADIRACHTIN

Assistant Commissioner for Patents
Washington, D.C. 20231

October 3, 2002

Sir:

Submitted herewith are an original and two copies of an Appeal Brief in the above-identified U.S. patent application.

Also enclosed is a Credit Card Payment form in the amount of \$320.00 to cover the cost of filing this Appeal Brief. In the event that any additional fees are due with respect to this paper, please charge Deposit Account No. 50-0925. This paper is filed in triplicate.

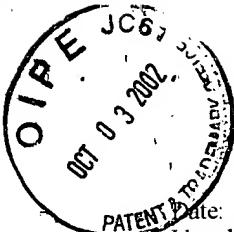
Respectfully submitted,
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Luke A. Kilyk

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of)
DAMARLA, et al.) Art Unit: 1616
Application Number: 09/536,351) Examiner: Levy, N.
Filed: March 27, 2000)

For: STORAGE STABLE PESTICIDE FORMULATIONS CONTAINING AZADIRACHTIN

Commissioner for Patents
Washington, D.C. 20231

October 3, 2002

APPELLANTS' BRIEF ON APPEAL

Sir:

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's February 5, 2002 Final Rejection of claims 1-12, 14-19, 23, and 24. The appealed claims are set forth in the attached Appendix.

I. THE REAL PARTIES IN INTEREST

The real party in interest besides the named inventors is E.I.D. Parry (India) Ltd.

II. RELATED APPEALS AND INTERFERENCES

No other appeal or interference which will directly effect or be directly effected by or have a bearing on the Board's decision in this appeal is known to the Appellants or to the Appellants' legal representative.

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III. STATUS OF CLAIMS

Claims pending in the application are claims 1-12, 14-19, 23, and 24. Claims 1-12, 14-19, 23, and 24 stand rejected.

A copy of the claims on appeal (claims 1-12, 14-19, 23, and 24) can be found in the Appendix.

IV. STATUS OF AMENDMENTS

One Amendment After Final was filed on May 3, 2002 after the Final Office Action of February 5, 2002. In the Advisory Action dated May 20, 2002, the Examiner indicated that the Amendment After Final would not be entered. The claims in the Appendix do not, therefore, incorporate this Amendment.

V. SUMMARY OF INVENTION

The claimed invention relates to pesticide formulations, and more particularly relates to pesticide formulations comprising at least one vegetable oil, at least one surfactant, and azadirachtin or a neem seed extract comprising azadirachtin. (*See*, for example, specification page 5, lines 13-14). According to the claimed invention, the pesticide formulations, comprising at least one vegetable oil, at least one surfactant, and azadirachtin or a neem seed extract comprising azadirachtin, are storage stable and contain substantially no water. The claimed invention also relates to pesticide formulations formed by mixing at least one vegetable oil, at least one non-ionic surfactant, and at least one neem seed extract, wherein the neem seed extract comprises at least azadirachtin and wherein the pesticide formulations contain substantially no water.

VI. ISSUES

The issues for review by the Board of Patent Appeals and Interferences are:

- A. Whether the Examiner was correct in rejecting claims 1-12, 14-19, 23, and 24 under 35 U.S.C. § 112, second paragraph on the basis that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention;

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B. Whether the Examiner was correct in rejecting claims 1-3, 5, 14, 17, and 19 under 35 U.S.C. § 102(b), on the basis that the claims are anticipated by European Patent Publication No. EP 0 579 624 B1 to Kleeberg (hereinafter "Kleeberg");

C. Whether the Examiner was correct in rejecting claims 1-7, 14-17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by an article authored by Dimetry et al., entitled "Synergistic effect of some additives on the biological activity and toxicity of neem-based formulations against the cowpea aphid, *Aphis craccivora* Koch", Insect Sci. Applic., 17(3/4): 395-99 (1997) (hereinafter "Dimetry et al.");

D. Whether the Examiner was correct in rejecting claims 1-5, 14, 15, 17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by an article authored by Schauer, entitled "Effects of variously formulated neem seed extracts on *Acrythosiphon pisum* and *Aphis fabae*", Proc. 2nd Int. Neem Conf. (Rauschholzhausen), pp. 141-50 (1983) (hereinafter "Schauer"); and

E. Whether the Examiner was correct in rejecting claims 1-12, 14-19, 23, and 24 under 35 U.S.C. § 103(a) on the basis that the claims are obvious over U.S. Patent No. 4,556,562 to Larson (hereinafter "Larson") in view of an article authored by Kleeberg et al. entitled "Analytical determination of Azadirachtin A and Azadirachtin B in neem extracts," In: Practice Oriented Results on Use and Production of Neem Ingredients and Pheromones, Proceedings of the 3rd Workshop, Ed H. Kleeberg, Duck & Graphic, Giessen, pp. 139-48, (1994) (hereinafter "Kleeberg et

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al."), Dimetry et al., and U.S. Patent No. 6,034,128 to Ujihara (hereinafter "Ujihara").

VII. GROUPING OF THE CLAIMS

As presently appealed, the grouping of the claims is as follows:

Claim 1 stands alone.

Claims 2, 3, 6, 7, 8, and 14 stand or fall together.

Claims 4, 12, 15, and 24 stand or fall together.

Claim 5 stands alone.

Claim 9 stands alone.

Claims 10 and 23 stand or fall together.

Claims 11 and 16 stand or fall together.

Claims 17, 18, and 19 stand or fall together.

VIII. ARGUMENTS

A. The Examiner's Rejection of claims 1-12, 14-19, 23, and 24 under 35 U.S.C. § 112, second paragraph, on the basis that the claims are indefinite for failing to particularly point out and distinctly claims the subject matter that Appellants regard as the invention.

1. The Examiner's Rejection.

On page 2 of the final Office Action, mailed February 5, 2002, the Examiner rejected claims 1-12, 14-19, 23, and 24 under 35 U.S.C. §112, second paragraph, on the basis that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention. The Examiner asserted that the word "substantially" is indefinite. More specifically, the Examiner stated that the Appellants assert that 2-5% water permits stability (at page 2, line 33 of the specification) then later, assert that 15% water constitutes "substantially no water" in terms of stability (at page 3, line 1 of the specification). The Examiner further alleged that the term "organic solvents" is also undefined since vegetable oil is an organic solvent. The Examiner also used U.S. Patent No. 5,352,697 to Butler et al. to support the Examiner's rejection of the claims and alleged that Butler defines storage stable azadirachtin differently from Appellants' definition.

For the following reasons, the Examiner's rejection should be reversed.

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2. Appellants' Reply to the Examiner's Rejection of claims 1-12, 14-19, 23, and 24 under 35 U.S.C. § 112, second paragraph, on the basis that the claims are indefinite for failing to particularly point out and distinctly claims the subject matter that Appellants regard as the invention.

With respect to the Examiner's rejection of the claims under 35 U.S.C. § 112, second paragraph, the following comments apply to each of the claims rejected under §112.

Insofar as the Examiner's remark regarding the terms "substantially," or "substantially no water," according to M.P.E.P. §2173.05(c), the term "substantially" is definite when used in conjunction with another term to describe a particular characteristic of the claimed invention (e.g. substantially no water). Furthermore, Appellants' remark about U.S. Patent No. 4,946,681, which reports greater stability for azadirachtin in solutions of aprotic solvents containing less than 2-5% water (page 2, lines 32-33) and about U.S. Patent No. 5,001,146, which indicates decreasing the water content to less than 15% by volume (page 3, line 1), are not examples of what is considered "substantially no water" for purposes of the claimed invention. These two patents are offered for background purposes and nowhere in the present application is there any mention that these particular percentages referenced by the Examiner are a definition of what is meant by the term "substantially no water" for purposes of the present application. Clearly, at the bottom of page 5 of the present application, examples of substantially no water are provided and preferably this amount includes less than about 2% by weight and even more preferably less than 1% by weight of water, based on the weight of the concentrate or formulation.

With respect to the term "organic solvent," the meaning of this term is clear to one having ordinary skill in the relevant art, especially in light of the portions of the specification quoted. An organic solvent does not include vegetable oil. To one of ordinary skill in the art, an organic solvent could be ethanol, xylene, and other organic solvents. Thus, the term "organic solvent" is a term widely recognized by those skilled in the art. For instance, Hawley's Condensed Chemical Dictionary (14th Ed.) (2001) clearly recognizes the term "organic solvent" and shows groups that include esters, ethers, ketones, amines, nitrated and chlorinated hydrocarbons, and the like. Clearly, this is quite different from a vegetable oil. In fact, the same Hawley's Condensed Chemical Dictionary defines vegetable oil in a manner that clearly would not be an organic solvent. Thus, the Examiner's position with respect to the term "organic

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"solvents" is not supported by any record and clear evidence has been submitted by the Appellants to show that the Examiner's position is not accurate.

With respect to the Examiner's reliance on U.S. Patent No. 5,352,697 to Butler et al., the Examiner relies on this patent to further support the Examiner's rejection under 35 U.S.C. §112 rejection. The Examiner asserted that Butler et al. shows a storage stable azadirachtin that describes storage stability differently from the present application. However, the Examiner's position still does not alter the fact that storage stability has been properly and fully described in the present application. As appreciated by the Examiner, storage stable is clearly described at page 7, lines 24-30. Thus, an example of storage stable has been provided by the Appellants in the present application. In view of the above, the rejection under 35 U.S.C. §112, second paragraph should be withdrawn.

The claimed invention, in part, is a pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin or a neem seed extract, wherein said formulation is preferably storage stable and contains substantially no water. The formulation of the present invention can be diluted with water or other medium at the site of use. The present invention provides a way to maintain a storage stable product that is easily useable when needed. The formulation of Butler et al. differs on the ground that Butler et al. does not show a formulation with substantially no water. The lack of water is an important feature of the claimed invention, since the presence of water is known to degrade azadirachtin, as is set forth at page 5, lines 19-23 of the present application. Degradation of azadirachtin due to water is also explained in an excerpt from the Pesticide Research Journal, dated 1999. Moreover, a Declaration from one of the inventors, namely, Dr. M.C. Gopinathan, shows that in the pesticide composition of the present invention, azadirachtin in sesame oil, remains stable compared to azadirachtin containing water. The Declaration of Dr. M.C. Gopinathan was submitted to the Examiner, along with Appellants' Amendment After Final, on May 3, 2002. The Declaration indicates that vegetable oil, like sesame oil, provides stability to azadirachtin in neem seed extracts, and if water is present in the composition it causes rapid degradation to azadirachtin.

Furthermore, the examples in Butler et al. use organic solvents instead of vegetable oils. For instance, example 1 of Butler et al. uses ethanol, ethyl, acetate, acetonitrile, isopropynol, methanol, and the like. Likewise, example 2 through example 10 of Butler et al. show azadirachtin containing neem seed extract in an aromatic petroleum distillate. In other words,

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none of the examples in Butler et al. illustrate the use of azadirachtin, at least one vegetable oil, and at least one surfactant wherein the formulation is storage stable and contains substantially no water. The advantages of not using organic solvents are illustrated at page 7, lines 31-33 of the present application.

All independent claims recite the limitation that substantially no water is present and, therefore, for the reasons set forth above, the claims are allowable. Accordingly, the rejection should be reversed.

B. The Examiner's Rejection of claims 1-3, 5, 14, 17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by Kleeberg.

1. The Examiner's Rejection.

On page 3 of the final Office Action, the Examiner rejected claims 1-3, 5, 14, 17, and 19 under 35 U.S.C. §102(b) on the basis that the claims are anticipated by Kleeberg (EP 0 579 624). The Examiner asserted that claim 1 of Kleeberg shows the present invention and that dilution is shown in claims 10 and 17 of Kleeberg.

For the following reasons, the Examiner's rejection should be reversed.

2. Appellants' Reply to the Examiner's Rejection of claims 1-3, 5, 14, 17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by Kleeberg.

a. The patentability of independent claim 1.

Kleeberg is substantially different from the claimed invention in several ways. First, Kleeberg does not teach or suggest the use of a vegetable oil, as in the claimed invention. This failure alone mandates the reversal of this §102(b) rejection.

Further, the Examiner's reliance on claims 10 and 17 of Kleeberg do not support a rejection of the claims. For instance, claim 9 of Kleeberg suggests using organic solvents such as ketones, alcohols (such as 1-butanol, pentanol), esters (such as acetic ethyl ester, acetic acid n-butyl ester) or halogenated hydrocarbons (such as dichloromethane, trichloromethane). Second, the material in Kleeberg is a powdery concentrate as suggested in claim 13 of Kleeberg. Additionally, unlike the claimed invention, the actual storage life of the material is not specified. As for the materials stored in the surfactant, it can only be stored for several months. Therefore, Kleeberg does not show a "storage stable" pesticide formulation, as that term is used in the claimed invention.

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With regard to claims 10 and 17 of Kleeberg, claim 10 refers to the ratios of solvent to water being 1:10 in the previous claims, and claim 17 refers to the case in which the azadirachtin-rich surfactant phase is diluted with water in a specified ratio. Both of these claims appear to refer to a step in the process of producing the product of claim 1 in Kleeberg. Claim 1 of Kleeberg recites the extraction step used to remove organic compounds from the raw plant material. Claims 10 and 17 do not recite a subsequent step involving the production of a multi-component pesticide formulation with the compounds specified in the claims, or the application of such a formulation to plant life. Therefore, these claims do not seem pertinent to the claimed invention. Accordingly, Kleeberg does not anticipate claim 1 and therefore the rejection should be reversed.

b. The patentability of independent claims 2, 3, and 14.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Furthermore, Kleeberg does not show or disclose a storage stable formulation that comprises at least one vegetable oil and at least one non-ionic surfactant. Accordingly, Kleeberg does not anticipate claims 2, 3, and 14 and therefore the rejection should be reversed.

c. The patentability of claim 5.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Moreover, Kleeberg does not show or disclose a storage stable formulation that comprises at least one non-ionic surfactant and at least one vegetable oil where the vegetable oil contains less than 1% by weight free fatty acid based on the weight of the vegetable oil. As stated, Kleeberg does not teach any vegetable oil at all. Accordingly, Kleeberg does not anticipate claim 5 and therefore the rejection should be reversed.

d. The patentability of claims 17 and 19.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Furthermore, Kleeberg does not teach a storage stable formulation that is substantially free of organic solvents, as recited in claims 17 and 19. To the contrary, Kleeberg, for instance in claim 9 of Kleeberg suggests using organic solvents such as ketones, alcohols (such as 1-butanol, pentanol), esters (such as acetic ethyl ester, acetic acid n-butyl ester) or halogenated

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hydrocarbons (such as dichloromethane, trichloromethane). Accordingly, Kleeberg does not anticipate claims 17 and 19 and therefore the rejection should be reversed.

C. The Examiner's Rejection of claims 1-7, 14-17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by Dimetry et al.

1. The Examiner's Rejection.

On page 3 of the final Office Action, the Examiner rejected claims 1-7, 14-17, and 19 under 35 U.S.C. §102(b) on the basis that the claims are anticipated by the Dimetry et al. article published in 1997. The Examiner asserted that Dimetry et al. shows an azadirachtin compound with a surfactant and sesame oil at designated percentages and dilution with water.

For the following reasons, the Examiner's rejection should be reversed.

2. Appellants' Reply to the Examiner's Rejection of claims 1-7, 14-17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by Dimetry et al.

a. The patentability of independent claim 1.

As recited in claim 1, the claimed invention relates to a pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin, wherein the formulation contains substantially no water. The Dimetry et al. formulation and the claimed invention differ on grounds that Dimetry et al. only shows a formulation with water, as can be seen from column 1 at page 396. However, the claimed invention contains substantially no water. As stated earlier, the lack of water is an important feature of the claimed invention, since the presence of water is known to degrade azadirachtin, as is set forth at page 5, lines 19-23 of the application and as set forth in the Declaration of Dr. M. C. Gopinathan.

Additionally, Dimetry et al. does not teach or suggest the use of a formulation having storage stable azadirachtin, which is recited in the claims. The formulation of Dimetry et al. is not storage stable because its formulation contains water, and, as previously noted, azadirachtin is unstable in the presence of water and other solvents. To further show this point, one of the inventors conducted comparative experiments to compare the claimed invention with Dimetry et al. As shown in the Declaration of Dr. M.C. Gopinathan submitted under 37 CFR §1.132, the formulation of Dimetry et al., which contained water along with small amounts of sesame oil and a surfactant, had a very low storage stability. In other words, the storage stability of the formulation of Dimetry et al. was poor compared to the product of the claimed invention that contained substantially no water. Thus, the formulation of Dimetry et al. is not a storage stable

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product and is different, for the reasons stated above, from the claimed invention. Accordingly, Dimetry et al. does not anticipate claim 1 and therefore the rejection should be reversed.

b. The patentability of independent claims 2, 3, and 14 and claims 6 and 7.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Furthermore, Dimetry et al. does not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant, as found in claims 2, 3, and 14 and claims 6 and 7. Accordingly, Dimetry et al. does not anticipate the claims and therefore the rejection should be reversed.

c. The patentability of claims 4 and 15.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Moreover, Dimetry et al. does not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant and sesame seed oil, as found in claims 4 and 15. Accordingly, Dimetry et al. does not anticipate the claims and therefore the rejection should be reversed.

d. The patentability of claim 5.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Furthermore, Dimetry et al. does not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant and at least one vegetable oil where the vegetable oil contains less than one (1) percent by weight free fatty acid based on the weight of the vegetable oil, as found in claim 5. Accordingly, Dimetry et al. does not anticipate the claim and therefore the rejection should be reversed.

e. The patentability of claim 16.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Dimetry et al. does not show or disclose a storage stable formulation that is substantially free of water and comprises sorbitan polyoxyethylene, as found in claim 16. Accordingly, Dimetry et al. does not anticipate the claim and therefore the rejection should be reversed.

f. The patentability of claims 17 and 19.

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The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Furthermore, Dimetry et al. does not show or disclose a storage stable formulation that is substantially free of water and is substantially free of organic solvents, as found in claims 17 and 19. Accordingly, Dimetry et al. does not anticipate the claims and therefore the rejection should be reversed.

D. The Examiner's Rejection of claims 1-5, 14, 15, 17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by Schauer.

1. The Examiner's Rejection.

On page 3 of the final Office Action, the Examiner also rejected claims 1-5, 14, 15, 17, and 19 under 35 U.S.C. §102(b) on the basis that the claims are anticipated by the Schauer article published in 1983. The Examiner asserted that Schauer shows a neem seed extract with synergistic sesame oil, lecithins, surfactant, and glycerol, and shows a formulation having insecticide properties, as recited at page 143 of the cited reference.

For the following reasons, the Examiner's rejection should be reversed.

2. Appellants' Reply to the Examiner's Rejection of claims 1-5, 14, 15, 17, and 19 under 35 U.S.C. § 102(b) on the basis that the claims are anticipated by Schauer.

a. The patentability of independent claim 1.

As explained previously, independent claim 1 requires the presence of substantially no water in the pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin. Therefore, there is a significant difference between the cited reference and the claimed invention. As set forth at page 142 of Schauer, the formulation is prepared by dissolving a tertiary-methyl-butyl ether extract ("MTB") in methanol and is further diluted with distilled water. Aqueous solution and various additives, such as glycerol, sesame oil, and two different lecithins are added. Schauer et al. teaches diluting the MTB extract with water prior to addition of sesame oil. Furthermore, Schauer et al. only teaches the use of an MTB extract as a neem seed; however, it does not teach or suggest that azadirachtin would be a significant component. In fact, Schauer et al. does not even mention azadirachtin. For this reason alone, the §102 rejection should be reversed.

Because the formulation used in Schauer et al. contains large amounts of water, it does not have any improved storage stability. As such, the cited article does not recite improved

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storage stability, which is a feature recited in the claims of the present invention. Accordingly, Schauer et al. does not anticipate the claim and therefore the rejection should be reversed.

b. The patentability of independent claims 2, 3, and 14.

The arguments provided above with regard to lack of anticipation are fully incorporated herein. Schauer et al. uses water in their formulation.

Furthermore, the use of lecithin in the formulation of Schauer et al. further degrades active ingredients due to its ionic properties. Therefore, not only does Schauer et al. not show or disclose a formulation comprising at least one non-ionic surfactant, as required in claims 2, 3, and 14, but the formulation of Schauer et al. is incompatible with the formulation of claims 2, 3, and 14. Accordingly, Schauer et al. does not anticipate the claims and therefore the rejection should be reversed.

c. The patentability of claims 4 and 15.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Moreover, Schauer et al. does not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant and sesame seed oil, as required in claims 4 and 15. Accordingly, Schauer et al. does not anticipate the claims and therefore the rejection should be reversed.

d. The patentability of claim 5.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Moreover, Schauer et al. does not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant and at least one vegetable oil where the vegetable oil contains less than one (1) percent by weight free fatty acid based on the weight of the vegetable oil, as found in claim 5. Accordingly, Schauer et al. does not anticipate the claim and therefore the rejection should be reversed.

e. The patentability of claims 17 and 19.

The arguments provided above with regard to lack of anticipation are fully incorporated herein.

Moreover, Schauer et al. does not show or disclose a storage stable formulation that is substantially free of water and is substantially free of organic solvents, as found in claims 17 and

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19. Accordingly, Schauer et al. does not anticipate the claims and therefore the rejection should be reversed.

E. The Examiner's Rejection of claims 1-12, 14-19, 23, and 24 under 35 U.S.C. § 103(a) on the basis that the claims are obvious over Larson in view of Kleeberg et al., Dimetry et al., and Ujihara.

1. The Examiner's Rejection.

On page 3 of the final Office Action, the Examiner also rejected claims 1-12, 14-19, 23, and 24 under 35 U.S.C. §103(a) on the basis that the claims are unpatentable over Larson (U.S. Patent No. 4,556,562) in view of the articles by Kleeberg et al., and Dimetry et al., and Ujihara (U.S. Patent No. 6,034,128). The Examiner asserted that Larson shows a storage stable azadirachtin containing surfactant, neem oil, and substantially no water or solvent, that is stable for up to two years. The Examiner concluded that it would have been obvious for a person of ordinary skill in the art to use Larson's composition with A and B constituents shown by Kleeberg et al., and with the adjuvant shown by Dimetry et al., to produce the claimed invention.

For the following reasons, the Examiner's rejection should be reversed.

2. Appellants' Reply to the Examiner's Rejection of claims 1-12, 14-19, 23, and 24 under 35 U.S.C. § 103(a) on the basis that the claims are obvious over Larson in view of Kleeberg et al., Dimetry et al., and Ujihara.

a. The patentability of independent claim 1.

The significance of the Ujihara reference to the present rejection is unclear because the Examiner does not specifically explain the relevance of this reference in the rejection, as it is not apparent from the examination of the reference itself. In the Advisory Action, mailed May 20, 2002, the Examiner stated Ujihara is cumulative. Ujihara relates to a compound used as an insecticide, but it does not seem to relate to azadirachtin or a component of neem seed oil. Additionally, in the November 20, 2001 response to an Office Action, the Appellants requested the Examiner to clarify the significance of the Kleeberg et al. reference, since the two forms of azadirachtin do not appear to be directly mentioned in the Kleeberg et al. reference as recited in claim 8 of the present application. As such, the Appellants can only conclude that the Kleeberg et al. reference is not material to this rejection.

Further, Larson relates to a method of extracting various active ingredients from neem seed, diluting the resultant extract to form an aqueous emulsion, and then adjusting its pH to a

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specific range. Larson specifically mentions the use of water. The presence of water as a diluent in Larson is shown at column 3, lines 53-63 and in claim 1. As such, the cited reference does not teach or suggest forming a storage stable pesticide concentrate that contains substantially no water. The formulation of Larson clearly includes water, which is different from the claimed invention. Therefore, Larson does not teach or suggest the claimed invention. Furthermore, one skilled in the art would not have a reason to look at any other publication in view of Larson, since Larson already provides a method to achieve storage stability, albeit, different from the claimed invention. Therefore, one of ordinary skill in the art would not seek to combine the teachings of Larson with any other reference to solve the stability problem, since Larson already provides a solution for that problem.

As stated previously, like Larson, Dimetry et al. forms a formulation using water with sesame oil. Since both Dimetry et al. and Larson have a formulation formed with water, one skilled in the art by reading Larson in view of Dimetry et al. would formulate a composition having water. None of the references or combination thereof teaches or suggests the presence of vegetable oil in the substantial absence of water. Also, the Examiner has not explained why one skilled in the art would assume that the addition of an oil in Larson or Kleeberg would not affect the long-term stability of the emulsion, nor has the Examiner explained why one skilled in the art would believe that sesame oil would be stable in the presence of solution described by Larson. Accordingly, the cited references, alone or in combination, do not render obvious the claim and therefore the rejection should be reversed.

b. The patentability of independent claims 2, 3, and 14 and claims 6-8.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

Furthermore, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant and at least one vegetable oil, as required in claims 2, 3, and 14 and claims 6, 7, and 8. Accordingly, the cited references, alone or in combination, do not render obvious the claims and therefore the rejection should be reversed.

c. The patentability of claims 4, 12, 15, and 24.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

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Moreover, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises at least one non-ionic surfactant and sesame seed oil, as required in claims 4, 12, 15, and 24. Accordingly, the cited references, alone or in combination, do not render obvious the claims and therefore the rejection should be reversed.

d. The patentability of claim 5.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

Moreover, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises a non-ionic surfactant and at least one vegetable oil where the vegetable oil has less than 1% by weight free fatty acid based on the weight of the vegetable oil. Accordingly, the cited references, alone or in combination, do not render obvious the claim and therefore the rejection should be reversed.

e. The patentability of claim 9.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

Furthermore, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises a non-ionic surfactant that is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one (1) year of storage at 25°C in a sealed container. Accordingly, the cited references, alone or in combination, do not render obvious the claim and therefore the rejection should be reversed.

f. The patentability of claims 10 and 23.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

Moreover, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises from about 20% to about 55% by weight of a non-ionic surfactant, from about 1% to about 5% by weight of azadirachtin, and from about 1% to about 60% by weight of vegetable oil or from about 20% to about 50% by weight of vegetable oil. For example, the sesame oil used in Dimetry et al. is below one weight percent, which is quite different from the amounts recited in claims 10 and 23

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of the present application. Accordingly, the cited references, alone or in combination, do not render obvious the claims and therefore the rejection should be reversed.

g. The patentability of claims 11 and 16.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

Moreover, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises sorbitan polyoxyethylene trioleate. Accordingly, the cited references, alone or in combination, do not render obvious the claims and therefore the rejection should be reversed.

h. The patentability of claims 17-19.

The arguments provided above with regard to non-obviousness are fully incorporated herein.

Moreover, the cited references, alone or in combination, do not show or disclose a storage stable formulation that is substantially free of water and comprises at least one surfactant and at least one vegetable oil, wherein the formulation is substantially free of organic solvents. Accordingly, the cited references, alone or in combination, do not render obvious the claims and therefore the rejection should be reversed.

F. Response to Advisory Action.

The Examiner issued an Advisory Action (Paper No. 8) mailed May 20, 2002 in which the Examiner indicated that Appellants' proposed Amendment After Final of May 3, 2002 will not be entered upon the filing of this Appeal. In addition, in the Advisory Action of May 20, 2002, the Examiner checked the box indicating that the Appellants' proposed amendment and response to the final Office Action had been considered but would not be entered, and the final rejections would stand, because the proposed amendment raised new issues that would require further consideration and/or search. Specifically, the Examiner stated that the proposed claims as amended would raise issues related to 35 U.S.C. § 112, and that proposed amended claim 9 would be redundant. The Examiner indicated that Appellants' Amendment After Final would have overcome the Examiner's rejections under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 102 related to the rejection of claims 2 and 3. The Examiner stated that Appellants' Declaration had been considered but did not overcome the Examiner's rejection because the Appellants' claimed invention is obvious. Accordingly, the Declaration is

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of record and the Board is respectfully requested to consider the weight of this Declaration in the reversing of the Examiner's rejections. The Examiner further stated that the Ujihara reference is cumulative.

IX. CONCLUSION

For at least the reasons discussed above, it is respectfully submitted that the Examiner's rejections of the pending claims are in error and should be reversed.

If there is any fee due in connection with the filing of this Brief on Appeal, please charge the fee to our Deposit Account No. 50-0925.

Respectfully submitted,

KILYK & BOWERSOX, P.L.L.C.



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Atty. Docket No. 3900-003

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APPENDIX

CLAIMS ON APPEAL

CLAIMS 1-12, 14-19, 23, and 24

WHAT IS CLAIMED IS:

1. (Amended) A pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin, wherein said formulation is storage stable and contains substantially no water.
2. A pesticide formulation comprising at least one vegetable oil, at least one non-ionic surfactant, and azadirachtin, wherein said formulation is storage stable and contains substantially no water.
3. (Amended) A storage stable pesticide formulation comprising at least one vegetable oil, at least one non-ionic surfactant, and a neem seed extract, wherein said neem seed extract comprises azadirachtin, and wherein said formulation contains substantially no water.
4. The formulation of claim 3, wherein said vegetable oil is sesame seed oil.
5. The formulation of claim 3, wherein said vegetable oil contains less than 1% by weight free fatty acid based on the weight of the vegetable oil.
6. (Amended) The formulation of claim 3, wherein said azadirachtin is present in said formulation in an amount of from about 0.1 to about 5.0 weight %, based on the weight of the pesticide formulation.

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7. (Amended) The formulation of claim 3, wherein said azadirachtin is present in said formulation in an amount of from about 0.1 to about 1.0 weight %, based on the weight of the pesticide formulation.

8. The formulation of claim 3, wherein said azadirachtin is azadirachtin A, azadirachtin B, or both.

9. The formulation of claim 3, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container.

10. (Amended) The formulation of claim 3, wherein said formulation comprises:

from about 1% to about 60% by weight of vegetable oil.

from about 1% to about 5% by weight azadirachtin;

and from about 20% to about 55% by weight of said non-ionic surfactant, based on the weight of the pesticide formulation.

11. The formulation of claim 10, wherein said surfactant is a sorbitan polyoxyethylene trioleate.

12. The formulation of claim 10, wherein said vegetable oil is sesame seed oil.

14. (Amended) A storage stable pesticide formulation formed by mixing at least one vegetable oil, at least one non-ionic surfactant, and at least one neem extract together to form said formulation, wherein said neem extract comprises at least azadirachtin, and wherein said formulation contains substantially no water.

15. The formulation of claim 14, wherein said at least one vegetable oil is sesame seed oil.

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16. The formulation of claim 15, wherein said non-ionic surfactant is sorbitan polyoxyethylene trioleate.

17. The formulation of claim 1, wherein said formulation is substantially free of organic solvents.

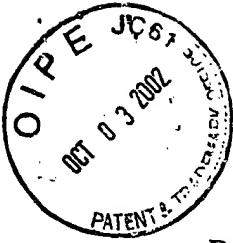
18. The formulation of claim 10, wherein said formulation is substantially free of organic solvents.

19. The formulation of claim 14, wherein said formulation is substantially free of organic solvents.

23. The formulation of claim 10, wherein said vegetable oil is present in an amount of from about 20 weight % to about 50 weight %; and

said surfactant is present in an amount of from about 40 weight % to about 50 weight %.

24. The formulation of claim 23, wherein said vegetable oil is sesame seed oil.



May 3, 2002
Date April 30, 2002 Label No. EV074199411US

I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

Dawn M. Berry
Name (Print)

Dawn M. Berry
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

)
DAMARLA, et al.

) Art Unit: 1616

) Application Number: 09/536,351

) Examiner: Levy N.

) Filed: March 27, 2000

For: STORAGE STABLE PESTICIDE FORMULATIONS CONTAINING AZADIRACHTIN

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

April 30, 2002

Sir:

I, Dr. M.C. Gopinathan do declare and state as follows:

- 1.) I am one of the named inventors of the above-identified U.S. patent application.
- 2.) I am also the Manager of Research and Development for E.I.D. Parry (India) Limited, who is the assignee of the present application. I have been employed by E.I.D. Parry (India) Limited for about 13 years.
- 3.) I am responsible for the research and development of products containing azadirachtin, and I am very familiar with the materials described and claimed in the present application. The examples set forth in the present application were prepared under my direct supervision.

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Declaration Under 37 C.F.R. §1.132
U.S. Patent Application No. 09/536,351

- 4.) I am very familiar with the present application and the communications received from the U.S. Patent & Trademark Office, including the Office Action dated February 5, 2002.
- 5.) This Declaration is submitted so that the Examiner can appreciate that the following experiments demonstrate the differences and unexpected superiority of the claimed invention over the cited references.
- 6.) Pesticide compositions containing neem seed extract (e.g., azadirachtin) and sesame oil were prepared under my direct supervision in the same manner as in the Examples of the present application. These compositions were tested to confirm that the sesame oil provides stability to azadirachtin in neem seed extracts, and that if any substantial water is present in the sesame oil composition, the water causes rapid degradation to azadirachtin.
- 7.) In more detail, the following test results illustrate that azadirachtin in sesame oil remains stable compared to azadirachtin containing water. This indicates that sesame oil provides stability to azadirachtin in neem seed extracts and that water, if present in the sesame oil composition, causes rapid degradation to azadirachtin.

Experiment 1

Stability of Azadirachtin in the formulation of Dimetry et al.

Objective : To demonstrate the higher stability of the formulation of the present invention compared to the Dimetry formulation.

To one part of the composition of the present invention, 10 parts of 0.6% of sesame oil (emulsified with 0.01% Tween 85) is added and mixed thoroughly to form a uniform suspension. The formulation was taken in a sealed flask and evaluated with respect to the stability of Azadirachtin under accelerated conditions, 54 Deg C. Rapid degradation of Azadirachtin (87.59%) was observed in the formulation compared to the formulation of the present invention (18.63%)

Sl.No.	Composition	Initial Aza	(%) Drop at 54 Deg C in 7 days
1	Azadirachtin extract + Tween 85 + Sesame oil (Composition of the present invention)	1.02	18.63
2	Dimetry formulation* (Composition of the present invention +0.6% sesame oil emulsified with 0.01% Tween 85, 1:10)	0.09*	87.59

*Dimetry et al. used a formulation containing 1.0% Azadirachtin and mixed 0.6% of sesame oil emulsified with 0.01% Tween. Hence Dimetry's composition contains around 0.09% Azadirachtin only, whereas the Azadirachtin content of present invention is 1.0%.

Result: The stability of Azadirachtin in the Dimetry formulation is far lower than the stability of Azadirachtin in the formulation of the present invention. It also demonstrates that the Dimetry et al. formulation is a ready to use formulation and is not a storage stable one.

As can be seen, the formulation of Dimetry et al. is not storage stable and is quite different from the storage stability of the present application as shown in the above experiment. Clearly, the use of small amounts of sesame oil along with water does not provide any storage stability, which is quite different from the claimed invention. In my opinion, Dimetry et al. clearly does not teach the present invention.

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Experiment 2

The following two compositions were prepared to evaluate the stabilizing effect of sesame oil on azadirachtin and the effect of water on the stability of azadirachtin in sesame oil.

- (i) *Composition of neem seed extract (azadirachtin) and sesame oil:* A saturated solution of the neem extract containing azadirachtin in sesame oil, used in the present invention, was prepared. The azadirachtin content of the composition was 0.9%. The stability of azadirachtin in this composition was evaluated at 54°C for 28 days.
- (ii) *Composition of sesame oil containing neem seed extract + Water:* Composition (i) was treated with 10% Tween 85 in water (20:1), mixed thoroughly and the stability evaluated.

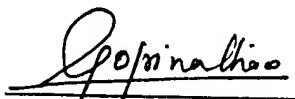
Sl.No.	Composition	Initial Azadirachtin	(%) Drop at 54°C in 28 days
1	Azadirachtin + Sesame oil (Mixed thoroughly and centrifuged to obtain clear solution)	0.11	11.8%
2	Sesame oil containing Azadirachtin + 10% Tween 85 in water(20:1)	0.10	64.0%

Conclusion

Azadirachtin in sesame oil remains stable (only 11.00% drop in 28 days at 54°C) compared to that containing water (64.0% drop in 28 days at 54°C). This indicates that sesame oil provides stability to azadirachtin in neem seed extracts, and that water present in sesame oil compositions causes rapid degradation to azadirachtin.

Declaration Under 37 C.F.R. §1.132
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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and any such willful false statement may jeopardize the validity of the application or any issuing thereon.


Dr. M.C. Gopinathan, General Manager (R& D)
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Date : April 30, 2002